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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,715	01/08/2004	Richard C. Gunderson	10527-525001	6270

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EXAMINER	
SEVERSON, RYAN J	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/753,715	GUNDERSON, RICHARD C.	
	Examiner	Art Unit	
	Ryan Severson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *20-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 44-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/04, 5/04, 7/05, 4/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election **without traverse** of species 4, claims 1-19 and 44-45 in the reply filed on October 27, 2006 is acknowledged.

2. Claims 20-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Election was made **without traverse** in the reply filed on October 27, 2006.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 152 (Figures 5A-5B), 182 (Figure 6A), 216 (Figures 7C and 8C), 307 (Figures 8B and 8C), and 318 (Figure 8C). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required

corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. Applicant is reminded of the proper content of an abstract of the disclosure:

> A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

> (1) if a machine or apparatus, its organization and operation;
> (2) if an article, its method of making;
> (3) if a chemical compound, its identity and use;
> (4) if a mixture, its ingredients;
> (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

5. The current abstract submitted by applicant does not disclose any technical information or include that which is new in the art to which the invention pertains.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4, 8-19, and 44-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The term "about" in claims 4, 8-10, 12, 13, 15, and 44 is a relative term that renders the claim indefinite. The term "about" in each of the above-mentioned claims precedes a dimensional range. It is suggested that applicant delete the term "about" from each of the above-mentioned claims to establish a finite dimensional range for the structures claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 1-3, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Loeffler (5,891,154).** Loeffler reference discloses the invention substantially as claimed, including: a "catheter" (12) and a "sheath" (10) surrounding the catheter with proximal and distal ends and an "orifice" (1 and/or 2) between the ends of the sheath (see Column 6, Lines 33-35). A "stent" (16) is disposed between the catheter and the sheath prior to implantation into the body lumen (see Figure 1).

Regarding claim 2, the sheath can contain multiple orifices (1 and 2).

Regarding claim 3, the stent strut inherently will have a maximum dimension (most likely the cross-sectional area) because it has a size. The orifices can be sized according to need (see Column 6, Lines 37-42) and therefore are capable of being sized smaller than the maximum dimension of the stent.

Regarding claim 6, Loeffler reference includes a stent (16).

Regarding claim 7, the stent of Loeffler reference is balloon (14) expandable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Loeffler (5,891,154) as applied to claim 1 above.** Loeffler reference discloses the invention substantially as claimed, including: a "catheter" and a "sheath" surrounding the catheter with proximal and distal ends and an "orifice" between the ends of the sheath.

A "stent" is disposed between the catheter and the sheath prior to implantation into the body lumen. Loeffler reference also discloses that the size of the orifices may be varied according to the need in the procedure (see Column 6, Lines 37-42). However, Loeffler reference does not disclose that the size of the orifice be specifically 0.02 inches or less. It would have been an obvious matter of design choice to make the orifices of Loeffler reference 0.02 inches or less, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

10. **Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Loeffler (5,891,154) as applied to claims 1 and 3 above, and further in view of Wilson et al. (6,425,898).** Loeffler reference discloses the invention substantially as claimed, including: a "catheter" and a "sheath" surrounding the catheter with proximal and distal ends and an "orifice" between the ends of the sheath. A "stent" is disposed between the catheter and the sheath prior to implantation into the body lumen. However, Loeffler reference does not disclose that the sheath contain multiple layers with at least one layer being a support material. Attention is drawn to Wilson et al. reference, which teaches a sheath may have multiple layers with one being a support layer to enhance stent deployment (see Column 8, Lines 12-19 for specific benefits). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the sheath of Loeffler reference with multiple layers, as taught by Wilson et al. reference, to enhance stent deployment.

11. **Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loeffler (5,891,154) as applied to claim 1 above.** Loeffler reference discloses the invention substantially as claimed, including: a "catheter" and a "sheath" surrounding the catheter with proximal and distal ends and an "orifice" between the ends of the sheath. A "stent" is disposed between the catheter and the sheath prior to implantation into the body lumen. Loeffler reference also discloses that the location of the orifices may be varied according to the need in the procedure (see Column 6, Lines 37-42). However, Loeffler reference does not disclose that the location of the orifice be specifically "at most 100 millimeters" (with regard to claim 8) and "at least 1 millimeter" (with regard to claim 9) from the distal end of the sheath. It would have been an obvious matter of design choice to modify Loeffler reference by locating the orifice a distance between 1 and 100 millimeters from the distal end of the sheath, since applicant has not disclosed that having the orifice located at this specific distance from the end of the sheath solves any stated problem or is for any particular purpose and it appears the delivery device would perform equally well with the orifices located as shown in figure 1 of Loeffler reference.

12. **Claims 10-14 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loeffler (5,891,154).** Loeffler reference discloses the invention substantially as claimed, including: a "catheter" (12) and a "sheath" (10) surrounding the catheter with proximal and distal ends and an "orifice" (1 and/or 2) between the ends of the sheath (see Column 6, Lines 33-35). A "stent" (16) is disposed between the catheter and the sheath prior to implantation into the body lumen (see Figure 1).

However, Loeffler reference does not disclose that the location of the orifice(s) be specifically "at most 100 millimeters" (with regard to claims 10 and 13) and "at least 1 millimeter" (with regard to claim 12) from the distal end of the sheath. It would have been an obvious matter of design choice to modify Loeffler reference by locating the orifice(s) a distance between 1 and 100 millimeters from the distal end of the sheath, since applicant has not disclosed that having the orifice(s) located at this specific distance from the end of the sheath solves any stated problem or is for any particular purpose and it appears the delivery device would perform equally well with the orifice(s) located as shown in figure 1 of Loeffler reference.

Regarding claim 11, the device of Loeffler reference can deliver the implantable medical endoprosthesis (stent) into the lumen of a patient (see Column 6, Lines 49-51).

Regarding claim 13, the sheath can contain multiple orifices (1 and 2).

Regarding claims 14 and 17-19, Loeffler reference includes a balloon (14) expandable stent (16). The stent strut inherently will have a maximum dimension (most likely the cross-sectional area) because it has a size. The orifices can be sized according to need (see Column 6, Lines 37-42) and therefore are capable of being sized smaller than the maximum dimension of the stent.

13. **Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Loeffler (5,891,154) as applied to claim 10 above.** Loeffler reference discloses the invention substantially as claimed, including: a "catheter" and a "sheath" surrounding the catheter with proximal and distal ends and an "orifice" between the ends of the sheath. A "stent" is disposed between the catheter and the sheath prior to implantation into the

body lumen. The orifice can be a distance between 1 and 100 millimeters from the distal end of the sheath according to design choice (as explained in claim 10 above). However, Loeffler reference does not disclose that the size of the orifice be specifically 0.02 inches or less. It would have been an obvious matter of design choice to make the orifices of Loeffler reference 0.02 inches or less, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

14. **Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Loeffler (5,891,154) as applied to claim 10 above, and further in view of Wilson et al. (6,425,898).** Loeffler reference discloses the invention substantially as claimed, including: a "catheter" and a "sheath" surrounding the catheter with proximal and distal ends and an "orifice" between the ends of the sheath. A "stent" is disposed between the catheter and the sheath prior to implantation into the body lumen. The orifice can be a distance between 1 and 100 millimeters from the distal end of the sheath according to design choice (as explained in claim 10 above). However, Loeffler reference does not disclose that the sheath contain multiple layers with at least one layer being a support material. Attention is drawn to Wilson et al. reference, which teaches a sheath may have multiple layers with one being a support layer to enhance stent deployment (see Column 8, Lines 12-19 for specific benefits). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the sheath of

Loeffler reference with multiple layers, as taught by Wilson et al. reference, to enhance stent deployment.

Regarding claim 16, Loeffler reference includes a stent (16). The stent strut inherently will have a maximum dimension (most likely the cross-sectional area) because it has a size. The orifices can be sized according to need (see Column 6, Lines 37-42) and therefore are capable of being sized smaller than the maximum dimension of the stent.

15. **Claims 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thornton (5,830,181).** Thornton reference discloses the invention substantially as claimed, including a guide catheter (11) having proximal and distal ends and at least one orifice (30) between the ends. However, Thornton reference does not disclose that the location of the orifice be specifically "at most 100 millimeters" from the distal end of the catheter (11). It would have been an obvious matter of design choice to modify Thornton reference by locating the orifice a distance less than 100 millimeters from the distal end of the sheath, since applicant has not disclosed that having the orifice located at this specific distance from the end of the catheter solves any stated problem or is for any particular purpose and it appears the delivery device would perform equally well with the orifices located as shown in figure 1 of Thornton reference.

Regarding claim 45, the catheter of Thornton reference contains multiple layers (18 and 19) with at least on layer being a support material (see Column 3, Lines 7-9). The support layer is interpreted to be layer 19 since it secures layer 18 (see Column 3, Lines 15-19).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure is as follows: 6,669,716 to Gilson et al.; 6,033,413 to Mikus et al.; 5,346,471 to Raulerson; 5,980,483 to Dimitri; and 5,772,669 to Vrba.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Thursday 7:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ryan Severson
November 15, 2006

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
11/20/06.